A global effort to identify viral and bacterial families that are anticipated to threaten public health

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World Health Organization

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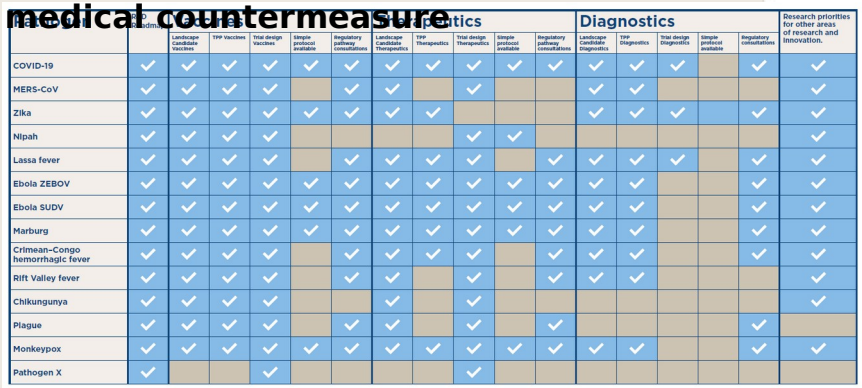
Background

- The R&D Blueprint leads research to accelerate the availability of safe and effective medical countermeasures for diseases that can cause a health emergency due to their epidemic or pandemic potential.
- Since its inception in 2015, an official list of priority diseases is regularly published to guide research priorities in WHO and the work of the R&D Blueprint.
- It was time for a rethink of the overall strategy

Approach for EACH priority pathogen and medical countermeasure



Priority pathogen	Platform technologies						Therapeutics					Diagnostics					Research priorities for other areas of research and innovation.
		Landscape candidate vaccines	TPP Vaccines	Trial design Vaccines	Simple protocol available	Regulatory pathway consultations	Landscape Candidate Therapeutics	TPP Therapeutics	Trial design Therapeutics	Simple protocol available	Regulatory pathway consultations	Landscape Candidate Diagnostics	TPP Diagnostics	Trial design Diagnostics	Simple protocol available	Regulatory consultations	
COVID-19	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
MERS-CoV	✓	✓	✓	✓		✓	✓		✓			✓	✓				✓
Zika	✓	✓	✓	✓	✓	✓	✓	✓				✓	✓	✓		✓	✓
Nipah	✓	✓	✓	✓					✓	✓							✓
Lassa fever	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓		✓	✓
Ebola ZEBOV	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓
Ebola SUDV	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓
Marburg	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓
Crimean–Congo hemorrhagic fever	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓			✓	✓
Rift Valley fever	✓	✓	✓	✓		✓	✓		✓		✓	✓	✓				✓
Chikungunya	✓	✓	✓	✓			✓		✓								✓
Plague	✓	✓	✓	✓		✓	✓		✓		✓					✓	
Monkeypox	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓
Pathogen X	✓			✓					✓								

- Priority Pathogen Identification
- Research Roadmaps, TPPs, global coordination
- Pipeline Monitoring
- Clinical trials and global toolbox (protocols, SOPs)

PREVIOUSLY… Pathogen, Products and Outbreak-Specific

MCMs
- o R&D Roadmaps
- o TPPs
- o Landscape of MCMs
- o Pathogen-specific trial design

Broader **Research and Innovation**

Collaborative **networks**

Trials integrated into the outbreak response

List of priority | **Pathogen-specific actions** | **Pathogen-specific trials during**

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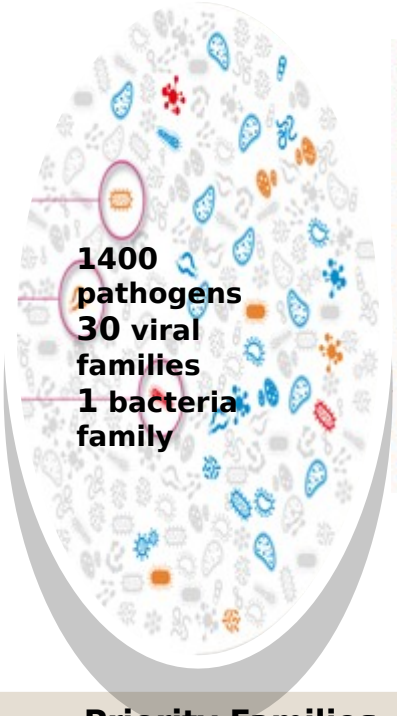
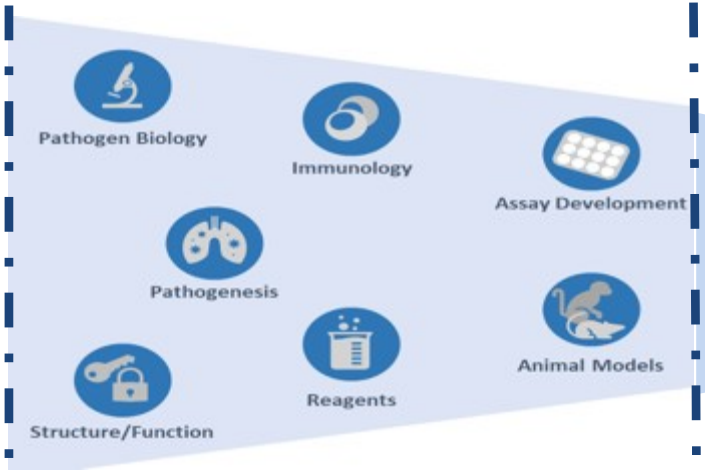
NOW… Viral and Bacterial Family approach





Trials integrated into the outbreak response

MCMs – prototype vaccines & therapeutics/Family

- o R&D Roadmaps
- o TPPs
- o Landscape of MCMs
- o CORE protocols /family trial design

Broader **Research and Innovation**

Trials to reduce **UNCERTAINTY** for important public health questions

Seamless trial design

Simple trial
Randomization during deployment

Priority Families
Prototype pathogens

ALL Families regardless of perceived pandemic potential

Phase 1- 2

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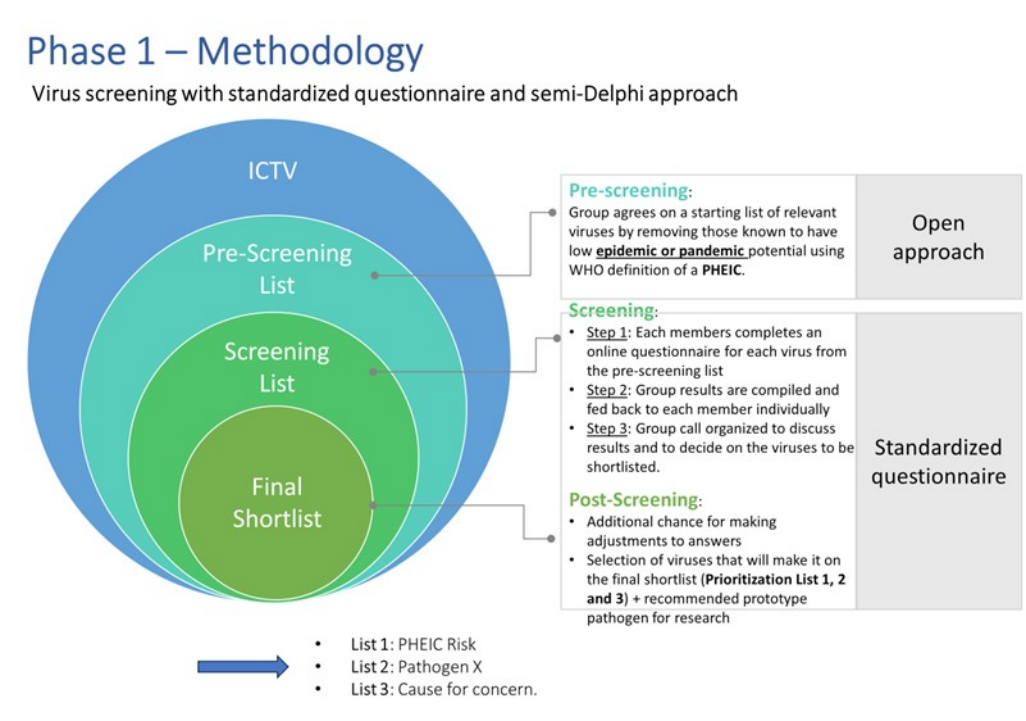
A new (agnostic) pathogen family approach

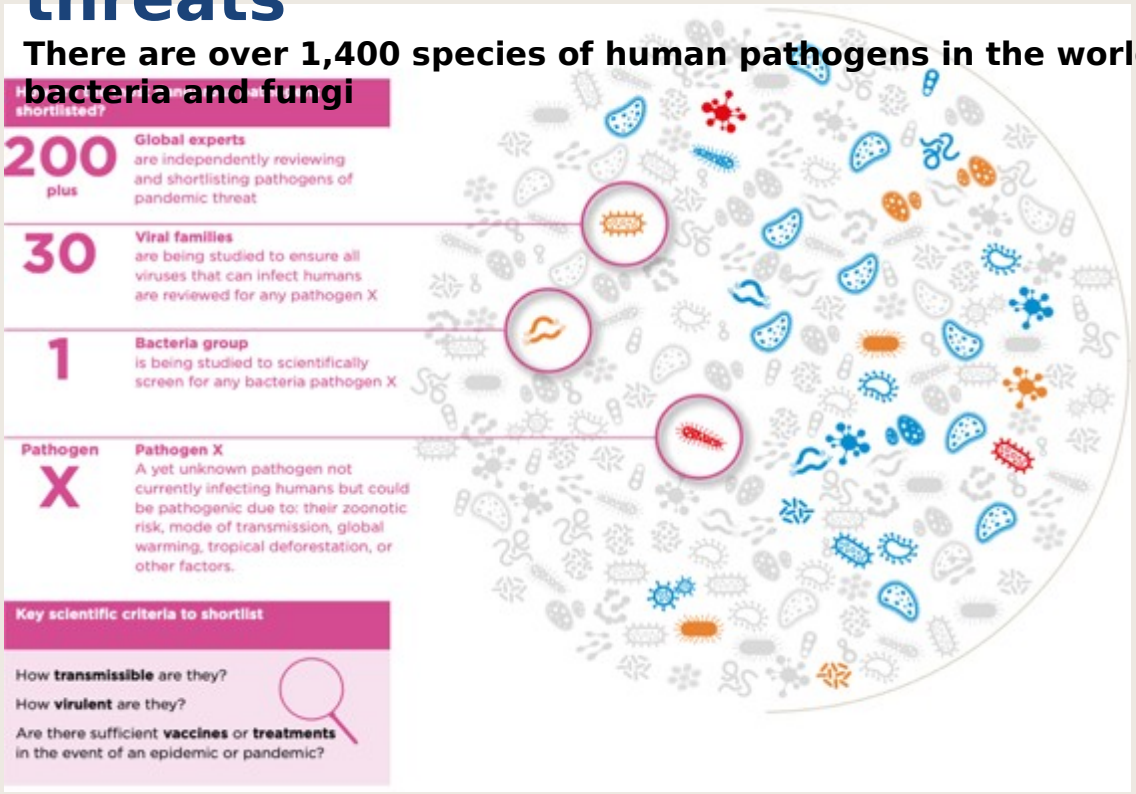
- A **pathogen family approach** has the advantage of encouraging research efforts on entire classes of viruses of concern, instead of on individual strains.

- The identification of a representative (or **prototype**) pathogen by family is a key component of the approach and used as pathfinder pathogen to prioritize research and the development of a vaccine or treatment that can apply to other pathogens in the same family.



Prioritizing the world's greatest pathogen threats

There are over 1,400 species of human pathogens in the world. These include virus, bacteria and fungi



Family reviewed and **not shortlisted**
Not likely to cause epidemic or pandemic, **or** already **equitable access** to safe & effective MCMs

Family reviewed and **not shortlisted**
Have epidemic or pandemic potential, **but** there is **equitable access** to safe &

Family reviewed and **shortlisted**
Have epidemic or pandemic potential, **and** there are **no or insufficient** MCMs

Family reviewed and **shortlisted**
Epidemic or pandemic potential is unknown, **but** shortlisted as potential **Pathogen X**

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Process for prioritizing the world's greatest pathogen threats

Phase 1

Scientific Prioritization

- Process: 30 independent viral family and 1 bacterial Working Groups
  2004 international experts
- Output: Not shortlisted and shortlisted viral and bacterial famil
  final prototype pathogen(s)

Dec 2022 – early 2024

Phase 2

Public Health Prioritization

- Process: Prioritization Advisory Committee (PAC)
  40 – 50 experts (including Chairs of WGs)
- Output: Final shortlist of viral and bacterial families with pandemic potential (incl. prototype pathogen(s)

Early 2024

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Next steps – 1/4 - A scientific approach to pandemic preparedness

Scientific opportunities to achieve fast and equitable access to high-

Scientific research priorities for all viral and bacterial families, regardless of perceived pandemic potential

- Defining the scope of **emerging virus treats** through the discovery
- Expanding generalizable **basic research** that would support the development of vaccines and therapeutics for future threats
- **Translational research** and product development with an eye on the potential for **generalizability**

Additional scientific research priorities for viral and bacterial families with pandemic potential

- Monitoring transmission of **pathogens known to cause outbreaks**
- Translational research and **product development** with an eye on potential for **generalizability**
- **Continue R&D projects** for identified pathogens with **generalizability** in mind
- Large, **simple** randomized **trials integrated into the outbreak response**

Additional scientific research priorities for an unknown pathogen (disease x) causing a pandemic

- Contemporary viral isolates that have been well characterized.
- Identifying antigens: scientific challenges
- Collaborative basic research to study viral structures for MCM development
- Evaluation of candidate MCMs using simple trials OR randomization during deployment, integrated into the outbreak response

GLOBAL COLLABORATION TO RESPOND TO AN UNKNOWN PATHOGEN (DISEASE X) CAUSING A PANDEMIC

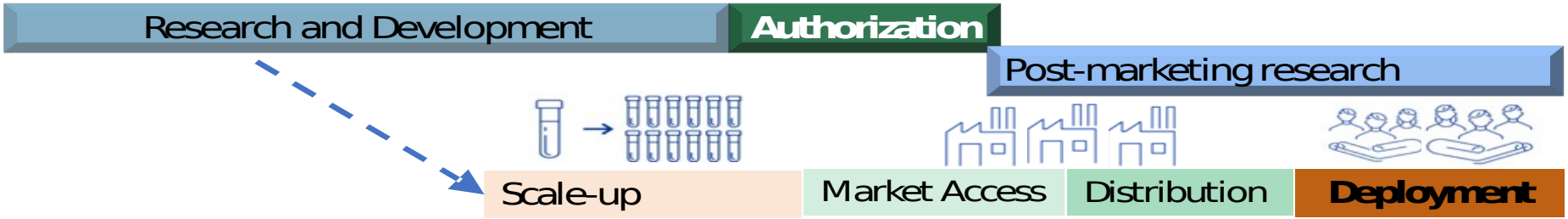
Next Steps – 2/4 - Prototype pathogen approach - for each viral family

11. Detailed Knowledge of viral characteristics

Natural immunity, correlates of protection, vaccine targets, atomic-level structures

2. Preclinical & clinical development of prototype vaccines & therapeutics

Vaccine/therapeutics modalities; phase 1, 2 immunogenicity, dose, schedule

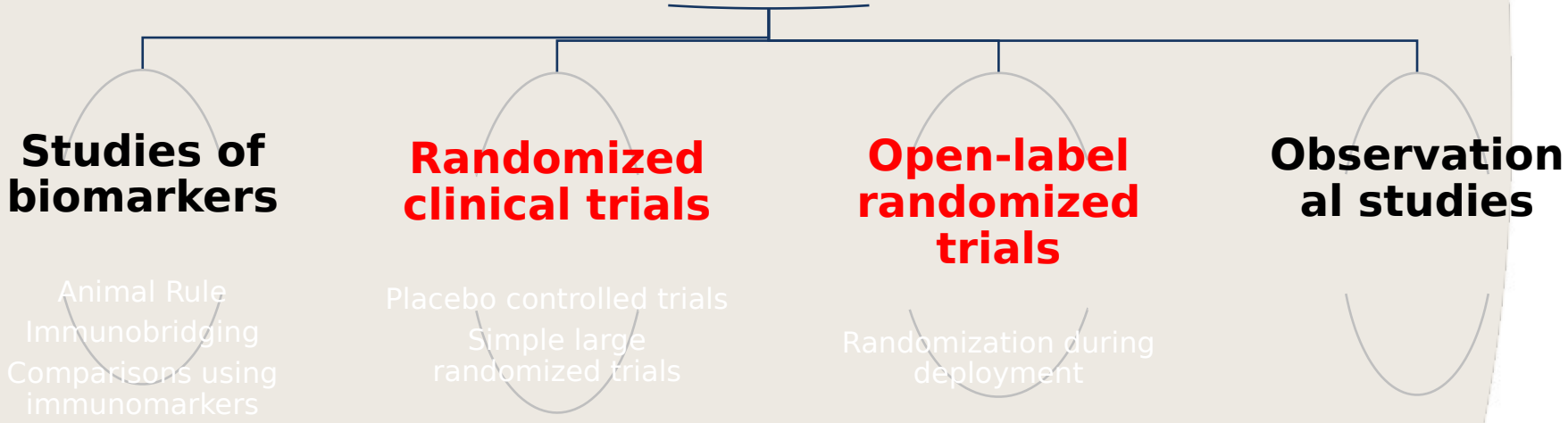


3. Manufacturing and storage

Platform engineering, formulation, scale, cold chain requirements

Next Steps – 3/4 - Study design options to reduce UNCERTAINTY during an epidemic

For candidate products that may have evidence on **safety** and may likely be **effective** against **outcomes important for public health,** but for which there is **remaining uncertainty**



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Next Steps – 4/4 - An approach to fast-track assessment of candidate MCMs

and support pandemic prevention and control

1 Prioritization

WHO Independent expert process to prioritize candidate vaccines

A WHO process for prioritization of candidate vaccines by an independent WHO Technical Advisory Groups on candidate vaccine and treatments prioritization

2 Availability

Agreement on availability and access to candidate vaccines and therapeutics

Decisions are informed by outcomes of the prioritization process on minimum number of candidate product doses required for research during outbreaks and that need to be available.

3 Clinical trials

CORE protocols and platforms to promptly initiate trials with equitable access to research

Ministries and researchers in affected countries are in the driving seat and integrated into the response. CORE protocols for viral and bacterial families design and approved in advance

4 Agreements

Prior agreement on legal collaboration, insurance, indemnity and liability

A partnership model and signed agreements with Ministries of Health and developers with **access** to MCMs considered, and a framework for insurance and liability arrangements.

5 Funding

Access to readily available funding through committed financing mechanism

Signed agreements with contributors; aimed at a simple approval process for releasing of funds and simplifying financial reporting.

6 Collaborative

To foster an open flexible collaborative mechanism that allows a variety of contributors

Including pathogen and trial experts, local researchers, and outbreak response teams to help adjust and implement research as needed

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The current challenges of Research and Innovation are a problem that can be solved.